

### **Remarks/Arguments**

#### **A. Status of the Claims**

Claims 64 and 65 were previously cancelled in Response filed on 7/12/06. Therefore, Applicants have added them back into the application as new claims 66 and 67. New claims 66 and 67 depend from pending claims to make them eligible for rejoinder under MPEP 821.04. Claim 68 has been added; support for this claim can be found in the specification at least at page 61, line 29 to page 32, line 5, and in FIG. 7 and Table 5. Thus, no new matter has been added.

#### **B. Objection to Claims for Reciting Non-Elected Subject Matter**

As previously stated on the record, claim 45 is a proper linking claim. 37 C.F.R. §1.141(a). Accordingly, the linked claims “must be examined with any one of the linked inventions that may be elected.” M.P.E.P. §814. Applicants are not required to amend the claims to remove recitations of non-elected subject matter so long as the linking claim is still pending. Applicants respectfully request that the objection to claim 54 be withdrawn.

#### **C. New Matter Objection**

The Action objects to the specification as containing new matter. Applicants respectfully traverse.

Claim 45 currently recites a “polypeptide comprising the amino acid sequence PIH<sup>L</sup>/<sub>R</sub>XVHW wherein X is a glycine, lysine or glutamic acid.” The specification provides written description for this claim. The specification expressly states:

In certain embodiments the size of the at least one proteinaceous molecule may comprise, but is not limited to, about or at least 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 275, 300, 350, 400, 450, 500, 550, 600, 650, 700, 750, 800, 850, 900, 950, 1000, 1100, 1200, 1300, 1400, 1500, 1750, 2000, 2250, 2500 or greater amino molecule residues, and any range derivable therein, particularly contiguous amino

acid sequences of such lengths from SEQ ID NO:2, SEQ ID NO:8, or SEQ ID NO:10. Page 31, line 29-page 32, line 5. (Emphasis added).

The underlined portions indicate that the specification contemplates a polypeptide with a sequence of eight contiguous amino acids from each of SEQ ID NOs: 2, 8 and 10. Claim 45 could have alternatively recited a polypeptide with the sequence PIHLGVHW from SEQ ID NO:2 (shown at position 527), PIHRKVHW from SEQ ID NO:8 (shown at position 392), or PIHLEVHW from SEQ ID NO:10 (shown at position 453). As discussed in previous responses, the generalized sequence in the claim is based on an alignment of SEQ ID NOs: 2, 8 and 10, which is shown in FIG. 7 and Table 5. These portions of the specification make it clear that the subject matter of claim 45 does not constitute new matter.

#### **D. Written Description Rejection**

The Action rejects claims 45-50 and 55-60 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement based on the alleged lack of written description. Claims 45-50 are rejected to the extent they recite a sentrin-specific protease comprising the amino acid sequence PIH<sup>L</sup>/<sub>R</sub>XVHW where X is glycine, lysine, or glutamic acid. Claims 55-60 have been similarly rejected. Applicants respectfully traverse.

The written description requirement may be “satisfied through sufficient description of a representative number of species . . . by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties . . . sufficient to show that applicant was in possession of the claimed genus.” MPEP § 2163, subsection 3(a)(ii), quoting from *Regents of the Univ. of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997).

As discussed in the section regarding new matter, the specification reasonably conveys to one of skill in the art that the inventors were in possession of a polypeptide comprising an amino

acid sequence of PIH<sup>L</sup>/R<sub>X</sub>VHW where X is a glycine, lysine, or glutamic acid because the specification sets forth the sequence of SEQ ID NOS: 2, 8, and 10, and it provides that contiguous amino acids from those sequences, including a segment of eight contiguous amino acids, are clearly contemplated. That disclosure alone should be sufficient to satisfy the written description requirement of every eight amino acid region in SEQ ID NO:2, 8, and 10. Moreover, in the present case, Applicants have also provided a figure (FIG. 7) and table (Table 5) comparing those sequences with one another to show their variation. This further confirms the nature of what Applicants had in their possession.

In addition, Applicants urge the examiner to consider his argument from a different perspective. If the present specification were an art reference against a claim like claim 45, by the examiner's reasoning, claim 45 would not be anticipated by the instant specification. Applicants are skeptical that the patent office would take this position because, as argued above, it is clear that the present disclosure teaches a polypeptide sequence with the recited "PIH<sup>L</sup>/R<sub>X</sub>VHW" sequence.

Moreover, Applicants contend that claim 68 recites a polypeptide having the sequence "PIHLGVHW, PIHRKVHW, or PIHLEVHW." This claim does not present new matter as this is shown in the provided SEQ ID NOS and in FIG. 7 and Table 5; moreover, the passage from the specification cited above makes it clear that the inventors were contemplating polypeptides that have a certain length of sequence from SEQ ID NOS:2, 8 and 10.

Based on the above arguments, Applicants respectfully request the withdrawal of the rejection.

#### **E. Claims 45-50 and 55-60 Are Enabled**

The Action rejects claims 45-50 and 55-60 under 35 U.S.C. § 112 for lacking enablement based on an alleged insufficient teaching. Applicants respectfully traverse.

In the specification, Applicants teach polypeptides with sequences having a “PIH<sup>L</sup><sub>R</sub>XVHW,” as recited in claim 45, through the disclosure of SEQ ID NO:2, SEQ ID NO:8 and SEQ ID N:10. In addition, the specification teaches a polypeptide having at least 25 contiguous amino acids of SEQ ID NO: 2 when it provides SEQ ID NO:2. Any high school student with a basic understanding of molecular biology and the SEQ ID NOs could generate a list of hundreds, if not thousands, of polypeptide sequences that meet the recitation of claims 45-50 or 55, 57-60. It is not clear how undue experimentation is required.

Moreover, the law does not require more than the sequences for enabling the presently claimed invention. “The enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)). Consequently, the specification satisfies the requirements of enablement.

Applicants further note that such polypeptides could be used for making antibodies and the Action does not provide any evidence of the contrary.

Accordingly, Applicants respectfully request this rejection be withdrawn.

#### **F. Anticipation Rejection**

The Action rejects claims 55-58 under 35 U.S.C. §102(b) based on Genbank Accession numbers AA236014 and AA330056, both of which are EST sequences. Applicants respectfully traverse.

Claim 55 recites an “isolated polypeptide comprising at least 25 contiguous amino acids of SEQ ID NO: 2.” As argued earlier, the EST sequences do not expressly teach the polypeptide of claim 55. Moreover, contrary to the assertion in the final office action, they do not “inherently” disclose any polypeptide sequence of SEQ ID NO:2. The MPEP states:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). MPEP 2112 (emphasis added).

The EST sequences fail to "necessarily" describe the recited polypeptide sequence because no frame for reading the nucleotide sequence is provided and three different polypeptide sequences are provided when the different frames are read. Furthermore, the appropriate polypeptide sequence is not obtained when the first nucleotide is taken as the translation frame. Consequently, not only do the cited EST sequences fail to expressly teach the claimed invention, but also, they do not inherently teach the claimed invention.

#### G. CONCLUSION

The Examiner is invited to contact the undersigned Attorney at (512) 536-3081 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Gina Shishima  
Reg. No. 45,104  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-3081  
(512) 536-4598 (facsimile)

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